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EXAMINER	
MOHAMED, ABDEL A	
ART UNIT	**PAPER NUMBER**
1653	10

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/636,491	NEU, JOSEF	
	Examin r	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,6 and 13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5, 6 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF AMENDMENT, REMARKS AND STATUS OF THE CLAIMS

1. The amendment and remarks filed 4/17/03 are acknowledged, entered and considered. In view of Applicant's request claims 4, 7-12 and 14-18 have been canceled and claims 1 and 13 have been amended. Thus, claims 1-3, 5, 6 and 13 are now pending in the application. The rejections under 35 U.S.C. 112, second paragraph and 35 U.S.C. 103(a) over the prior art of record are withdrawn in view of Applicant's amendment, remarks and cancellation of claims filed 4/17/03. However, the rejections under 35 U.S.C. (102(b) over the prior art of record for claims 1-3 and 5-6 and 35 U.S.C. 112, first paragraph for claim 13 are maintained.

2. The rejection under 35 U.S.C. 112, first paragraph with respect to composition claims 1-3, and 5-6 and method claims 14-18 is withdrawn in view of Applicant's remarks, amendment and cancellation of claims. However, amended method claims 13 and issues argued by Applicant in regard to claim 13 are maintained for the same reasons discussed on the previous Office action as they apply to current amended claim 13 as reiterated below:

CLAIMS REJECTION-35 U.S.C. § 112 FIRST PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 remains rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instantly claimed invention as currently amended in claim 13 is directed to a method for promoting an increased mucosal IgA immune response in a human or animal, said method comprising administering to a human or animal an effective amount of a dipeptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein the arginine residue is the amino terminus of said dipeptide and the glutamine residue is the carboxyl terminus of said peptide. Applicant's teachings do not adequately explain the evidence of using a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation for promoting increased mucosal immune response in a human or an animal as claimed in claim 13.

In this regard, the application disclosure and claim has been compared *per* the factors indicated in the decision *In re Wands*, 8 USPQ2 1400 (Fed. Cir. 1988) as to enablement and undue experimentation. The factors include:

1) the nature of the invention;

2) the breadth of the claim;

3) the predictability or unpredictability of the art;

4) the amount of direction or guidance presented;

5) the presence or absence of working examples;

6) the quantity of experimentation necessary;

7) the state of the prior art; and

8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claim and state of the prior art in the assessment of enablement (i.e., to make and/or use the invention).

1) the nature of the invention;

The instantly claimed invention as amended in claim 13 is directed to a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein said formulation is administered in a method for promoting increased mucosal IgA immune response (i.e., effective increased mucosal IgA immune responses) in an animal or a human.

2) the breadth of the claim;

The scope of the claim include a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation administered in a method for promoting an increased mucosal IgA immune response in a human or animal. The specification does not disclose one reasonable method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim because Applicant's teachings do not adequately explain the evidence of using the peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation for promoting an increased mucosal IgA immune response in a human or animal in the manner claimed in claim 13 in the instant invention.

Further, the first paragraph of 35 U.S.C. 112 requires, *inter alia,* that a patent specification provides sufficient guidance to enable a person skilled in the art to make and use the claimed invention without undue experimentation. *In re Vaeck,* 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991). While patent Applicants are not directed to disclose every species that falls within a generic claim, *id.* At 496, 20 USPQ2d at 1445, it is well settled that "the scope of the claims must bear a reasonable correlation to the scope of the enablement provided by the specification". *In re Fisher,* 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

3) the predictability or unpredictability of the art;

As admittedly acknowledged on page 2, lines 23-29 in the instant specification and as taught by Madsen et al. (U.S. Patent No. 5,189,016), experiments involving the use of total parenteral nutrition (TPN) containing glycyl-glutamine dipeptide (Commercial name Dipeptiven) and alanyl-glutamine dipeptide (Commercial name Glamin), suggest potential adverse effects of the TPN formulation containing the above commercially available dipeptide. The instant specification states to this date, there are no studies of the claimed arginyl-L-glutamine dipeptide. Further, on page 3, lines 6-8, the instant specification acknowledges by stating that there remains a great need in the art for compositions and methods which promote healthy muscle tissue, reduce muscle deterioration and/or promote a healthy immune system. However, on page 4, lines 22-26, the instant specification states that among the advantages of the dipeptide of the subject invention (i.e., arginyl-glutamine) over the existing commercially available alanyl-glutamine and glycyl-glutamine dipeptide is that the arginine moiety is particularly advantageous because it is a creatine phosphate precursor, a stimulator of immune

function, a stimulator of growth hormone production and, in combination with glutamine, is particularly useful in strengthening mucosal immune defenses. Nevertheless, there is no data or evidence in the instant specification to substantiate the above statement.

Furthermore, the reference of Neu et al., The FASEB Journal, Vol. 10, pp. 829-837, June 1996 (i.e., Neu is the inventor of the instantly claimed invention), the reference under the title "Glutamine nutrition and metabolism: Where do we go from here?" reviews concepts of glutamine biochemistry, metabolism, and nutrition. On page 834, left column, the reference states that the mechanisms for these beneficial effects (i.e., glutamine biosynthesis activity) remain poorly understood, but these studies offer a stimulus for further investigation. On the same page, right column, the reference concludes by stating this is an interesting area for future studies designed to explore the mechanism of benefits derived from glutamine supplementation. An improved understanding of these mechanisms could be applied to several other critical disease processes where glutamine supplementation or metabolism may play a role. Thus, clearly suggesting for further investigation of glutamine as a potentially useful as nutritional supplementation in promoting effective immune response.

Moreover, Moinard et al. (Journal of Leukocyte Biology, Vol. 67, pp. 834-840, June 2000) discloses the involvement of glutamine, arginine, and polyamines in the action of ornithine-ketoglutarate (OKG) on macrophage functions in stressed rats, wherein an oral administration of an equimolar amount of glutamine failed to reproduce the OKG-mediated effect. The result demonstrated by underlining the complexity of the mechanism of action of OKG, which can differ according to the functions of even a single cell type. Similarly, the reference of Robinson et al. (Clinical Science, Vol. 97,

No. 6, pp. 657-669, 1999) describes the comparisons of glutamine, arginine, and OKG. In theory, these nutrients are metabolically interconvertable by known pathways, each potentially being a biosynthetic precursor of the others. Since, it is not clear which of Arg, Gln and OKG is most critical to anti-tumor defense, and since they have not been compared systematically with one another in an internally controlled study, their relative efficacy is difficult to estimate (See e.g., page 658, left column, last paragraph). On page 667, under "Diet and immune function" the reference states that unfortunately, the design of most studies has been such that it is not possible to draw conclusions as to the efficacy of individual nutrients for improving immunity. Thus, clearly showing the unpredictable nature of compounds in the method of promoting effective immune responses in a human or animal in the manner claimed.

4) the amount of direction or guidance presented;

The specification discloses protocols and incorporates references improperly as recited on pages 1-6 in the instant disclosure for a peptide composition comprising an arginyl-glutamine dipeptide formulated as a nutrient formulation and a method for promoting increased immunity in a human or animal by administering said formulation thereof. However, there is no evidence or data to show that a similar regimen can be used for promoting an increased mucosal IgA immune response in a human or animal using the dipeptide thereof in the manner claimed in claim 13.

5) the presence or absence of working examples;

The instant specification does not enable for a method for promoting an increased mucosal IgA immune response in a human or animal, said method comprising administering to a human or animal an effective amount of a dipeptide

composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein the arginine residue is the amino terminus of said dipeptide and the glutamine residue is the carboxyl terminus of said peptide. Thus, Applicant's teachings do not adequately explain the evidence of making and using claimed dipeptide for a method of promoting an increased mucosal IgA immune response in a human or animal because there are no working examples or data in the instant specification substantiating the use of the above dipeptide for the method claimed in the instant invention; except for protocols.

6) the quantity of experimentation necessary;

In view of the fact that animals and humans are out bread, in view of the fact that the related dipeptide have potentially adverse effects as acknowledged on page 2, lines 23-29 in the instant specification, in view of the fact that the instant specification lacks working example(s), and in view of the recognized problems and particular need in the art for using dipeptide compositions for methods which promote an increased IgA immune response in a human or animal; a reasonable doubt exists as to the enablement of the claimed method for promoting increased immune responses, particularly in all kinds of animals including humans. The claims are based on pure speculation that the methods would be effective. Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as broadly claimed is enabled, since promotion of an increased mucosal IgA immune response in all kinds of animals and humans by administering presumably novel dipeptide is contemplated and is encompassed as well as a wide range of situations. The results desired appear to be highly dependent on all variables, the relationship of which is not

clearly disclosed. Hence, for the reasons discussed above, Applicant has not established any *nexus* between the claimed dipeptide useful in promoting an increased IgA immune response in all kinds of animals including humans (i.e., there is no therapeutic evidence or data in the instant application to support such claim). Thus, Applicant should present some data or authorative references in order to fulfill 35 U.S.C. 112, first paragraph requirement. For further support, See also *In re Coilliani*, 561 F. 2d 220, 195 USPQ 150 (CCPA 1977) and *Ex parte Forman* 230 USPQ 546 (BPAI 1986). Therefore, one of skill in the art would not be able to identify a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation intended to be effective to promote an increased mucosal IgA immune response in a human or animal as encompassed in the instantly claimed invention would be effective and under what conditions.

7) the state of the prior art;

Thus, in view of the above and in view of the fact that the state of the prior art as admittedly acknowledged by Applicant on page 2, lines 23-29 that experimentally involving use of TPN containing glycyl-glutamine dipeptide (related dipeptide to the instantly claimed dipeptide) suggest potential adverse effects and to this date, there are no studies of the claimed dipeptide arginyl-glutamine. Hence, one of skill in the art would not accept the characterization of any and all effective immune responses by administration of the dipeptide claimed protocols without working example(s) or data or evidence as believable on their face.

8) the relative skill of those skilled in the art;

Therefore, applying the Wands factors to the facts of this case, one of skill in the art would find that undue amount of experimentation would be required to practice the full scope of the claimed invention for the reasons given above. Thus, in view of the quantity of experimentation necessary, the lack of adequate guidance or working examples or data, and the breadth of the claim; the claim is not commensurate in scope with the enabling disclosure. Hence, in consideration of each of factors 1-8, it is apparent that there is undue experimentation because of variability in prediction of outcome that is not addressed by the present application disclosure, examples, teachings, and guidance presented. Therefore, Applicant has not disclosed to one of ordinary skill in the art how to use a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation for promoting an increased IgA immune response to all kinds of animals including humans. There is insufficient written description of the invention with respect to the *in vivo* enablement of the methods to enable one of ordinary skill in the art to use Applicant's invention for the reasons discussed above. Accordingly, the requirement of 35 U.S.C. 112, first paragraph of "how to use" has not been met. Therefore, it is viewed that the specification does not enable the invention as claimed in claim 13, as it does not teach how to use the invention to achieve the function of the claims.

CLAIMS REJECTION-35 U.S.C. § 102(b)

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-6 remain rejected under 35 U.S.C. 102(b) as being anticipated by JP2119762.

JP2119762 discloses a nutrient composition formulated with an essential amino acid and at least one oligopeptide selected from the group consisting of a dipeptide wherein the dipeptide is arginyl-glutamine (See e.g., page 7, line 12), wherein said formulation is suitable for enteral administration (See e.g., page 8, line 6), wherein said formulation is suitable for parenteral administration (See e.g. page 11, last two lines), and wherein said nutrient formulation comprises additives such as glucose, electrolyte, vitamins and trace elements (See e.g. ,page 15, paragraph 2). Thus, the reference clearly discloses a peptide composition comprising an arginyl-glutamine dipeptide formulated as nutrient formulation in the manner claimed in claims 1-3 and 5-6.

With respect to the concentration of claim 1 as amended, the concentration is not disclosed in the prior art in the manner claimed; however, the claim as drafted recites a wide range of concentration of dipeptide (i.e., from about 0.1% to about 25.%) by weight of the formulation; and does not define the concentration weight as functional limitation, rather, the claim defines the concentration weight as properties of the dipeptide formulation. Thus, it is the Examiner's position that a peptide composition comprising an arginyl-glutamine dipeptide formulated as a nutrient formulation would have the same concentration percentages by weight of said formulation as claimed, and as such, the concentration percentages is an inherent properties of the prior art dipeptide

composition. Thus, in the absence of evidence to the contrary, the nutritional formulation disclosed by the reference anticipates claims 1-3 and 5-6 as drafted.

ARGUMENTS ARE NOT PERSUASIVE

CLAIMS REJECTION-35 U.S.C. § 112 FIRST PARAGRAPH

5. The rejection of claim 13 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant's arguments filed 4/17/03 have been fully considered but they are not persuasive. Applicant has argued that 1) the Examiner has not made a *prima facie* case for lack of enablement; 2) the legal standard imposed by 35 U.S.C. § 112, first paragraph has been met because the subject application provides ample guidance for a person skilled in the art to make and use the subject invention as claimed; 3) the claims now presented are quite narrowly tailored. The claims recite one specific dipeptide for use in a very simple method to enhance a specific type of immunity, particularly, the claims have been amended herein to specify that the enhanced immunity is achieved by increasing mucosal IgA immunity; and 4) concludes by stating that the invention involves simple composition that is easily formulated and administered, and as such, the claim is fully enabled by the specification as originally filed, and that the requirements of the first paragraph of 35 U.S.C. § 112 have been met is not persuasive. With respect to the composition/formulation claims, the rejection for composition/formulation claims is withdrawn in view of Applicant's amendment, remarks

and cancellation of claims filed 4/17/03. However, the instantly claimed invention as currently amended in claim 13 is directed to a method for promoting an increased mucosal IgA immune response in a human or animal, said method comprising administering to a human or animal an effective amount of a dipeptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein the arginine residue is the amino terminus of said dipeptide and the glutamine residue is the carboxyl terminus of said peptide. Applicant's teachings do not adequately explain the evidence of using a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation for promoting increased mucosal immune response in a human or an animal as claimed in claim 13. Contrary to Applicant's arguments as discussed above that there is no evidence or data to show that the specification discloses one reasonable method for using the claimed invention that bears a reasonable correlation to the entire scope of the claim because Applicant's teachings do not adequately explain the evidence of using the peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation for promoting an increased mucosal IgA immune response in a human or animal in the manner claimed in claim 13 in the instant invention. Thus, the claimed invention is not enabled and speculative in that there is/are no working example(s) or data or evidence which shows that the claimed peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein said formulation is administered in a method for promoting increased mucosal response (i.e., effective increased mucosal IgA immune response) in an animal or a human.

Thus, in view of the discussion above and in view of the fact that there is no working example or data or evidence which shows that the claimed dipeptides are useful as nutrient formulation in the method of promoting an increased mucosal IgA immune response as claimed in claim 13. There is no evidence in the instant specification to use or administer the nutrient formulation in therapeutically effective amount as claimed, except for the mere recitation of protocols on pages 1-6 in the instant specification. Hence, the only support for using the claimed nutrient formulation in the specification in a method of promoting increased immunity thereof is Applicant's supposition of the invention as recited in the protocols. Thus, in view of the above, it would include those that have not been shown or taught to be useful or enabled by the disclosed method of making and using the invention. Moreover, undue experimentation is necessary to determine if and under what conditions, the claimed invention as claimed in claim 13 is enabled. The results desired appear to be highly dependent on all variables, the relationship of which is not clearly disclosed. Hence, one of ordinary skill in the art would not be able reproduce all the aspects the claimed invention method for promoting an increased mucosal IgA immune response in a human or animal as encompassed in the claim would be effective and under what conditions.

Therefore, in view of the above, the enablement of a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation, wherein said formulation is administered in a method for promoting increased mucosal IgA immune response (i.e., effective increased mucosal IgA immune responses) in an animal or a human as encompassed in the claim would be effective and under what conditions. The Examiner is unable to determine the enablement of the

invention as claimed without appropriate working examples. The only support for the claimed invention in the specification is Applicant's supposition of the invention and the improper incorporation of several publications supporting the protocols disclosed in the instant specification. Secondly, the Examiner has clearly shown in the previous Office Action of Paper No. 7 (mailed 12/17/02) and as discussed above that without guidance through working example(s), one of ordinary skill in the art would not predict from background discussion and/or information and protocols to employ or administer the nutrient formulation in therapeutically effective composition in the manner claimed. Thus, the specification does not enable any person skilled in the art to which it pertains, or which it is most nearly connected, to use the invention commensurate in scope with the claim. In the express absence of one or more examples, evidence and sufficient guidance, the skilled artisan would be faced with undue experimentation for practicing the invention. Thirdly, it is not understood from Applicant's response how the instant invention, which Applicant considers as novel and inventive, be exemplified without working example(s) or data or evidence. The law requires that a disclosure in an application shall inform those skilled in the art how to use Applicant's alleged discovery, not how to find out how to use it for themselves. See *In re Gardner et al.*, 166 USPQ 138 (CCPA 1970). Therefore, undue experimentation is necessary to determine if and under what conditions, the claimed invention as claimed is enabled. Hence, it is viewed that the specification does not enable the invention as claimed in claim 13, as it does not teach how to use the invention to achieve the function of the claims for the reasons discussed above. Thus, applying the Wands factors to the facts of this case, one of skill

in the art would find that undue amount of experimentation would be required to practice the full enablement of the claimed of invention of claim 13 for the reasons given above.

Therefore, Applicant has not disclosed to one of ordinary skill in the art how to use a peptide composition consisting essentially of an arginyl-glutamine dipeptide formulated as a nutrient formulation for promoting an increased IgA immune response to all kinds of animals including humans. There is insufficient written description of the invention with respect to the *in vivo* enablement of the methods to enable one of ordinary skill in the art to use Applicant's invention for the reasons discussed above. Accordingly, the requirement of 35 U.S.C. 112, first paragraph of "how to use" has not been met. Therefore, it is viewed that the specification does not enable the invention as claimed in claim 13, as it does not teach how to use the invention to achieve the function of the claims.

CLAIMS REJECTION-35 U.S.C. § 102(b)

6. The rejection of claims 1-3 and 5-6 under 35 U.S.C. 102(b) as being anticipated by JP2119762.

Applicant's arguments that the prior art of JP2119762 does not, either explicitly or inherently, disclose a composition that consists essentially of the arginyl-glutamine dipeptide at the claimed concentration is unpersuasive. Contrary to Applicant's arguments independent claim 1 as amended recites a wide range of concentration of dipeptide (i.e., from about 0.1% to about 25.%) by weight of said formulation; and the reference of JP2119762 on page 8 last paragraph and Table 1 disclose the concentration of a dipeptide having 24.2 gm dipeptide/100 gm which is

equal to 2.42% by weight because 1 ml of water (H2O) is equivalent to 1.0 gm STP. Therefore, 1 liter is equivalent to 1000 gm and 24.2 gm dipeptide/100 gm would be 2.42 % by weight, and as such, the nutrient formulation of the reference is in a concentration within the scope of the concentration recited in claim 1. Thus, in the absence of evidence to the contrary, the nutritional formulation disclosed by the reference anticipates claims 1-3 and 5-6 as drafted.

The following is a new ground of rejection necessitated by Applicant's amendment:

7. It is noted that the rejection under 35 U.S.C. 102(b) as being anticipated by Miyazawa et al., for claims 1-3 has been modified to include claims 5 and 6. This is not a new rejection since Applicant has received the 102(b) rejection over the same reference previously relied only on the abstract. Now, the Examiner is able to obtain the entire article and the rejection is based on the entire reference for claims 1-3 and 5-6. Further, Applicant has amended independent claim 1 by incorporating the limitation of canceled claim 4 (not included in the previous rejection, i.e., claims 1-3) and because of the amendment, a new ground of rejection is necessitated. Thus, this does not preclude the Examiner from making this Office action Final and the Examiner will respond to Applicant's arguments as they apply to the rejection set forth.

8. Claims 1-3 and 5-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Miyazawa et al. (Journal of the Faculty of Fisheries and Animal Husbandry Hiroshima, Vol. 15 No. 2, pp. 161-169, 1976).

The reference of Miyazawa et al. discloses a peptide composition comprising an arginyl-glutamine dipeptide formulation in large quantities from 7 species of marine green algal extracts, wherein *Ulva pertusa* was newly found to contain a dipeptide, L-arginyl-L-glutamine, in a considerable amount. The fresh specimens of the amino acid composition of the extract were kept in 3 volumes of ethanol for 1 week at room temperature on occasional stirring, respectively. The obtained ethanolic extracts were condensed under reduced pressure in order to remove ethanol and were defatted with diethylether (See e.g., page 161). On Table 1, the reference shows the arginyl-glutamine composition extract form *Ulva pertusa* and *Enteromorpha linza* to be 110.0 and 35.0 N ug in 1 g of fresh algae, respectively. Also, on page 163, second paragraph, the reference states that the L-arginyl-L-glutamine dipeptide was predominant and accounted for about 20 % of total nitrogen of the extract. Thus, clearly meeting the limitation of claim 1 concentration of dipeptide. Further, algae are known to be used for aquatic and marine food chains. Thus, for the aquatic and marine animals, the algae including the arginyl-glutamine dipeptide claimed are a nutrient formulation because the aquatic and marine animals eat the algae, and as such, the reference meets the limitation of a nutrient formulation comprising an arginyl-glutamine dipeptide as claimed in claim 1.

The reference does not disclose the intended use of the formulation is suitable for enteral administration (claim 2), and the formulation is suitable for parenteral administration (claim 3), respectively. Nevertheless, a statement of usefulness or contemplated use of a claimed compound or composition in a claim is usually given little weight in distinguishing over the prior art. *In re Maeder et al.* (CCPA 1964) 337 F2d

875, 143 USPQ 248; *In re Riden et al.* (CCPA 1963) 318 F2d 761, 138 USPQ 112; *In re Sinex* (CCPA 1962) 309 F2d 488, 135 USPQ 302. Further, it is well established that the intended use of a compound (e.g., a polypeptide or a protein or a glycoprotein) does not impart patentability to the compound. *In re Spada,* 911 F.2d 70, 15 USPQ2d 1655 (Fed. Cir. 1990) (The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition); *In re Pearson*, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claims patentable); *In re Zierden*, 411 F.2d 1325, 1328, 162 USPQ 102, 104 (CCPA 1969).

With respect to claim 5, the reference at page 161 indicates that the extracts were defatted, and as such, the extract without deflating contained fats which is anticipatory of claim 5. Further, since the composition is from algae extract it would be reasonable to conclude that the composition would also contain minerals and/or trace elements as recited in claim 5. In addition, the reference teaches that the algal specie contains a biological pathway for glucogenesis (makes glucose), and as such, the extract would have contained glucose, which is monosaccharide meeting the limitation of claim 6. Thus, in the absence of evidence to the contrary or specific structural limitations, the claimed composition/product disclosed by the reference anticipates claims 1-3 and 5-6 as drafted.

ACTION IS FINAL, NECESSITAYED BY AMENDMENT

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

CONCLUSION AND FUTURE CORRESPONDANCE

10. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703)

308-4242 for regular communications and (703) 305-7401 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

AAM
July 10, 2003

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600